REMARKS/ARGUMENTS

This amendment is submitted in response to the Office Action dated June 8, 2004. After entry of this amendment, claims 1-4 and 8-12 will be pending in the application. Amended claim 1 is includes subject matter of original claims 1 and 2 and further clarifies the language found in the original claims. New claim 9 includes the subject matter of original claims 5 and 6 and further clarifies the language found in the original claims. Amended claims 2-4 and new claim 8 incorporate the subject matter of original claims 2-4. New claims 10-12 incorporate the subject matter found in original claims 5-7. No new matter has been added to any of the amended or newly submitted claims.

Reconsideration and allowance is respectfully requested in view of the amendments made and the remarks made below.

1. The Specification

The Examiner requested a translated copy of reference NL-B-1 005572. A complete English translation is not available for this document. Attached to this amendment is an English abstract of NL-B-1 005572. This abstract and the description of this document in the present application as originally filed provide all relevant information on the content of NL-B-1 005572. However, if the Examiner prefers to have an English translation, such a translation can be provided, but the applicant would prefer to avoid making such a translation due to the cost..

The Office Action objected to the specification on the basis of a few minor informalities. The Applicant has amended the specification to comply with the Office Action's suggested corrections. The Applicant respectfully submits that the specification is now in proper format.

2. The §112 Second Paragraph Rejections

Claims 1-7 were rejected in the Office Action under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Office Action rejected claims 1, 2, 5, and 6, because the term "preferably" renders the claims indefinite because it is unclear whether the limitations following the term are part of the claimed invention. Newly amended claim 1 and new claim 9 have removed the term "preferably." The terminology following "preferably" has been rewritten and incorporated into dependent claims 2, 3, 10, and 11. Furthermore, the applicant has replaced the term "measuring" with the term "integrating." Support for this change can be found on page 6, line 24 through page 7, line 16 of Applicant's specification. The Applicant believes that these amendments have removed any § 112 issues found in the claims and requests acknowledgement to this effect.

The Examiner also indicated that he agrees with the international searcher's opinion that claims 1 and 5 are confusing "since applicant is claiming that a first variation in a indicator value is measured prior to injection of the indicator and thus the claim is considered confusing when in the art indicators are sometime dyes and the like."

The Applicant's invention relates to obtaining information from the living human body. The information obtained is thereafter used in a diagnostic method. The term "indicator" refers to a substance that has been injected into the body. However, it should be emphasized that the injected indicator is not a foreign substance, as foreign substances cannot be used in view of their toxic character. The indicator used in the method and apparatus of the invention is a substance naturally occurring in the human body. It is by virtue of this natural occurrence in the human body that the invention aims to provide compensation of the effects of variations in the indicator value, which are necessarily a part of the measurement of the change in the indicator value caused by the injection.

As explained in the original specification at page 1, line 32 through page 2, line 14, it is not the variation in the cardiac output caused by the heart action, but the variation caused by artificial respiration for which the invention aims to compensate. With respect to possible indicator substances reference is made to page 4, lines 36-38 of the specification. Clearly,

temperature, saline concentration, glucose concentration and color of blood can, and generally will, vary without any injection of an indicator. In Applicant's invention these natural variations are removed from the measurement in the period T_1 by determining the variation of the indicator value both directly prior to the injection in the period T_2 and in the period T_3 directly contiguous to the period T_1.

Therefore, the Applicant submits that the wording found in the claims is not confusing and requests that if the Examiner maintains such an opinion, that the Examiner present a more detailed explanation as to what specific claim language is considered to be confusing and why.

Accordingly, the Applicant believes that all §112 issues have been addressed and respectfully requests the removal of the §112 rejections.

3. The Rejections under 35 U.S.C. § 103(a)

Claims 1-2 have been rejected under 35 U.S.C §103(a) as being unpatentable over U.S. Patent No. 5,797,398 to Bowman (hereinafter "Bowman") in view of U.S. Patent No. 4,595,015 to Jansen et al. (Hereinafter "Jansen"). The Applicant submits that neither Bowman, nor Jansen, either in combination or alone, teaches every limitation of independent claim 1, or new independent claim 9.

Bowman discloses a method and apparatus that utilizes a different measurement than the method and apparatus according to Applicant's invention and required in claims 1 and 9. In Bowman the measurement is shown in figure 3 and the complete measurement cycle is shown in figure 6. A description of the method, identified as Process I, is given in column 5, line 35 up to column 6, line 28. The steps of Process I are first performed when the source of thermal energy is turned off and the average temperature difference per cycle is determined and stored. The sampling time at which this average temperature is determined is shown in figure 6 as the sample time period S1.

In Bowman, the heater is turned on for a specific time period and the temperature difference rises over a transition or delay rise time period shown in figure 6 as D1. After this delay rise time the temperature difference generally stabilizes over a second sample time period S2. After the heater is turned on and the temperature has stabilized, process I is performed again

over a number of cycles and the averaged temperature difference is determined with the heater turned on, and is stored.

As Bowman states in column 6, lines 14-39, cardiac output is calculated using the averaged temperature differences when the energy is off and the averaged temperature differences when the energy is on. This means that one complete measurement cycle in Bowman includes the delay in rise time that extends at least along several respiration cycles. Moreover a further delay in the fall time period has to occur before the next measurement can be made. This will result in a relatively long measuring period and a required delay time before a measurement can be repeated.

In Bowman, if an average temperature difference per respiration cycle were used, a process cycle with a heater on time and a heater off time of only one respiration cycle would be impossible. In Bowman the heater needs to be turned on and off, respectively, for a number of respiration cycles.

The method according to the Applicant's invention differs significantly from the method found in Bowman. In the Applicant's method an indicator is injected into the patient's blood stream over a period of substantially one respiration cycle. As explained above, in the method of Bowman a delay rise time D1 is needed after turning on the heater, this delay rise time corresponds to a number of respiration cycles.

In the Applicant's method the change in the indicator value, which in the example described is the temperature in the blood stream downstream of the injection point, is integrated over a measurement period T_1 of a number of respiration cycles. Furthermore a first variation in the indicator value is integrated over at least substantially a period T_2 of one respiration cycle prior to the injection and a second variation in the indicator value is integrated over the period T_3 of at least substantially one respiration cycle after the measurement period T_1. The average of the first and the second integrated variations is determined. Then the change in the indicator value as caused by the injection is determined on the basis of the difference between the change in the indicator value integrated over the measurement period T_1 and n times the average of the integrated first and second variations. The cardiac output is determined on the basis of the determined change in the indicator value, the amount of the indicator injected into the blood and the initial value thereof.

As illustrated in figure 3, the Applicant's method determines the area A, which is the area determined by the points a-d in figure 3 and the area C, which is the area determined by the points g–j, and takes the average of these areas. Furthermore the area B is determined, which is the area determined by the points c, d, g, and h. The cardiac output is determined by the difference between the area B and n/2 x (A+C). In this manner all variations in the indicator value caused by natural or artificial respiration are removed from the measuring result, so that only the change in the indicator value caused by the injection is obtained. By integrating the variation indicator value in this manner, it is possible to restrict the measuring period significantly. Moreover a new measurement can be started immediately after a previous measurement. Bowman is not able to accomplish this because, as noted above, Bowman will require delay time before a measurement can be repeated.

Therefore, Bowman does not teach or suggest the limitations found in independent claims 1 and 9. Furthermore, Jansen fails to correct the deficiencies found in Bowman and is merely used in the Office Action to illustrate a conventional thermal dilution system.

The Applicant respectfully submits that neither Bowman nor Jansen teach nor suggest the limitations of independent claims 1 and 9 and requests notification as to their allowance. Furthermore, the Applicant submits that claims 2-4 and 8-12 are allowable by virtue of their dependence upon allowable base claims.

4. Conclusion

Applicant has made an earnest effort to place this application in condition for allowance. If the Examiner feels that a telephone interview would expedite prosecution of this patent application, he is respectfully invited to telephone the undersigned at 215-599-0600.

Respectfully submitted,

Kevin J. Dunleavy
Registration no. 32,024

Date: September 8, 2004

KNOBLE YOSHIDA & DUNLEAVY, LLC
Eight Penn Center- Suite 1350
1628 John F. Kennedy Boulevard
Philadelphia, PA 19103
(215) 599-0600